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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,983	09/12/2000	Robert Hans Meloen	4518US	6015

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SALT LAKE CITY, UT 84110

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/18/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/659,983

Applicant(s)

MELOEN ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,10-12,15,27,28 and 55-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,10-12,15,27,28 and 55-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Status of Application, Amendments and/or Claims

The amendment filed 30 December 2002 (Paper No. 30) has been entered in full. Claims 1-4, 20, 21, 26, 34-36, 51 and 52 were cancelled. New claims 55-59 were added. Claims 5, 10-12, 15, 27, 28, 55-59 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objections to the specification as set forth at page 2 of the previous Office Action (30 July 2002, Paper No. 28) is *withdrawn* in view of the amendment (30 December 2002, Paper No. 30).

The rejection of claims 20, 21, 51 and 52 under 35 USC 112, first paragraph, enablement as set forth at pages 3-4 of the previous Office Action (30 July 2002, Paper No. 28) is *withdrawn* in view of the amendment (30 December 2002, Paper No. 30).

The rejection of claims 4 and 26 under 35 USC 112, first paragraph, scope of enablement as set forth at pages 5-6 of the previous Office Action (30 July 2002, Paper No. 28) is *withdrawn* in view of the amendment (30 December 2002, Paper No. 30).

The rejection of claim 4 under 35 USC 112, second paragraph, as set forth at pages 5-6 of the previous Office Action (30 July 2002, Paper No. 28) is *withdrawn* in view of the amendment (30 December 2002, Paper No. 30).

The rejection of claims 1-3, 10-12, 15, 34 and 35 under 35 USC 103(a) as being unpatentable over Alston-Mill *et al.* in view of Dufour *et al.* as set forth at pages 7-9 of the previous Office Action (30 July 2002, Paper No. 28) is *withdrawn* in view of the amendment (30 December 2002, Paper No. 30).

Claim Rejections - 35 USC § 112, first paragraph, enablement

Claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 27 is drawn to a peptide comprising a modified tandem GnRH decapeptide sequence capable of inducing an immunogenic response that allows for discrimination between different types of GnRH, said peptide comprising at least two coupled GnRH decapeptide sequences wherein at least one of the amino acids of said coupled GnRH decapeptide sequences is replaced by a different amino acid, and selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, and SEQ ID NO:7.

Claim 28 is drawn to a peptide comprising a modified tandem GnRH decapeptide sequence comprising a different amino acid comprising Ala, said peptide capable of inducing an immunogenic response that allows for discrimination between different types of GnRH and selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, and SEQ ID NO:7.

The specification teaches exact alanine and dextrorotatory lysine substitutions in specific GnRH decapeptides. Serine at position 4 was replaced with alanine and glycine at position 6 was replaced with dextrorotatory lysine (tandem GnRH decapeptide, SEQ ID NO:5). Arginine at position 8 was replaced by alanine and glycine at position 6 was replaced with dextrorotatory lysine (tandem GnRH decapeptide, SEQ ID NO:6). Glycine at position 10 was replaced with alanine and glycine at position 6 was replaced with dextrorotatory lysine (tandem GnRH decapeptide, SEQ ID NO:7) (page 14, lines 23-30). These specific sequences were demonstrated in the specification to have the function of inducing an immunogenic response that allowed for discrimination between GnRHI and GnRHII and inducing various effects in pigs (results, pages 22-27).

The subject matter sought to be patented as defined by the claims is not supported by an enabling disclosure because the specification fails to teach how to make and/or use all modified tandem GnRH decapeptide. The claims as recited read on any amino acid residue being replaced by any different amino acid (including alanine) at any number of positions in SEQ ID NO:5, SEQ ID NO:6 and SEQ ID NO:7. Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change and the nature and extent of changes that can be made in these positions.

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and screen same for activity, the lack of direction/guidance presented in the specification regarding same, the absence of

Art Unit: 1647

working examples (other than for SEQ ID NOs: 5, 6 and 7) directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, first paragraph, written description

Claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification provides adequate written description for SEQ ID NOs: 5, 6 and 7 but not substitution of any amino acid residue with any different amino acid at any position in SEQ ID NOs: 5, 6 and 7.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Art Unit: 1647

With the exception of SEQ ID Nos:5, 6 and 7, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. None of these sequences meet the written description provision of 35 USC 112, first paragraph. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NOs:5, 6 and 7 but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

No claims are allowed.

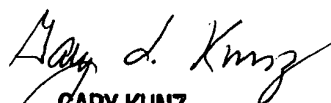
Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD
April 16, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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